UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,673	07/20/2000	BRUCE PAUL DAGGY	C75087	9337

7590 05/17/2007

DARA L DINNER
SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY UW2220
709 SWEDELAND ROAD
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/600,673	DAGGY ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,21-27 and 29-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19, 21-27, 29-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 2/7/2007 is acknowledged. Claims 20 and 28 were cancelled. Claims 35-48 were added.

Claims 19, 21-27, and 29-48 are pending and examined on the merits.

Claim Rejections Maintained and New Grounds of Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 19, 21-27 and 29-48 are/remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection is that one of skill in the art cannot use the specification to make or use the claimed inventions without undue experimentation.

Applicant's arguments have been carefully considered but fail to persuade. Applicant points to an experiment shown in the specification that demonstrates an effect of methylcellulose on aberrant crypt foci (ACF) formation in rats that had been injected with azoxymethane (a carcinogen). However, in view of the state of the art that indicates that animal models do not

correlate with human epidemiological data (teachings of Baron, discussed in previous Office action), it appears that the guidance provided by the specification is insufficient to support the claimed methods, where the intended use of the claimed methods is for the prevention of either colon cancer or breast cancer. Applicant also argues that because Baron is published 6 years later than the filing date of this application, it is not prior art to the instant application and that it is not valid to use it in a rejection of the claims. However, applicant is reminded that in a rejection under 35 U.S.C. 112, first paragraph, the Office may cite references with a publication date that is after the filing date of the application if the reference cited is for the purpose of demonstrating what one of skill in the art would have known at the time the application was filed. "In general, the examiner should not use post-filing date references to demonstrate the patent is non-enabling. Exceptions to this rule could occur if a later-dated reference provides evidence of what one skill in the art would have known on or before the effective filing date of the patent application." See MPEP 2164.05(a). In this case, a comparison was made between the claims, which are drawn to treatment of humans, and the data provided in the specification, which is from a rat model. Baron teaches that animal models to do not correlate with human epidemiological data. Therefore, Baron provides evidence that data provided in the specification would not lead one of skill in the art to have a reasonable expectation of success in practicing the methods as claimed for the purpose of preventing colon cancer or breast cancer in humans.

The examiner acknowledges the references provided by applicant in the response and notes that the Davis abstract appears to present data that is the same as that found in the specification, and that the Yokoyama reference does not present any data having to do with the intended use of the claimed methods, which intended use is the prevention of colon cancer or the

prevention of breast cancer. Therefore, it does not appear that applicant has provided any references or arguments that rebut the teachings of Baron.

Additionally, it is noted that in the previous Office action, the examiner discussed the lack of support in the specification for the intended use of prevention of breast cancer. The experiment pointed to by applicant in the response is an experiment to examine the effect of fiber on the development of colorectal cancer (because the endpoint measured was the number of abberant crypt foci). Thus, the specification also does not appear to provide guidance with respect to effect of methylcellulose and prevention of breast cancer, because the working example is directed to prevention of colorectal cancer in rats. Additionally, as discussed in the previous Office action, in the art, there appears to be a lack of consensus for the effect of fiber in general and no information with regard to the specific fiber, methylcellulose and the prevention of breast cancer. One study reports no effect of dietary fiber and the prevention of breast cancer (see Cho, W. et al. Cancer Epidemiology, Biomarkers & Prevention, 12: 1153-1158, 2003; page 1153, abstract and also 2nd column, 2nd paragraph). Another study does support an effect of dietary fiber in general (see Mattisson, I., et al., British Journal of Cancer , 90: 122-127, 2004; page 122, abstract), however, the results are for dietary fiber in general and not specifically to methylcellulose. Dietary fiber is often ingested in the form of whole grains and the protective effect of ingesting fiber may be related to other nutrients found in whole grains and not merely to presence of fiber. Slavin (Slavin, J., Proc. Nutr. Soc., 62(1): 129-134, 2003; abstract only) teaches that whole grains are sources of fiber, and additionally antioxidants, trace minerals, phenolic compounds, phytate, and phyto-estrogens, which are also nutrients associated with disease prevention.

Applicants argue that a lack of consensus is not a suitable ground for rejection. Applicants appear to misunderstand the rejection of record. The evidence offered by the present specification for the treatment of humans for the prevention of cancer is in the form of experiments in rats, whereas the claims are drawn to the treatment of humans. Therefore, for the specific intended use of the claimed methods (reducing the incidence of cancer in humans), the specification does not provide a working example. Additionally, the art of using dietary fiber to prevent cancer is not a predictable art, as evidenced by the references of record, leading to a lack of consensus. Therefore, it does not appear that the animal model provided by the specification is predictive of the intended use of the claimed methods.

Additionally, because the intended use of the claimed methods is for the reduction of the incidence of either colorectal cancer or of breast cancer, the claimed methods read on methods to prevent cancer. Thus, the claimed methods require administration of the methylcellulose compositions prior to the development of cancer. However, the specification provides no guidance for determining the appropriate time prior to the development of tumors or for identifying patients at risk for developing these tumors. Therefore, in view of the discordance between the support provided in the specification and the intended use of the claimed methods, where the support in the specification is for a decrease in aberrant crypt foci in rats treated with fiber over a short amount of time, whereas the claims are for the treatment of humans for the prevention of colorectal cancer or the prevention of breast cancer (which might be over a very long amount of time); and further in view of the fact that art concerning the use of fiber in the prevention of cancer does not indicate that the effect of fiber may reside in the ingestion of a specific, purified fiber such as the compositions comprising methylcellulose recited in the

claims, one of ordinary skill in the art would have engage in further and undue experimentation in order to practice the claimed methods. The further experimentation required would relate to the invention itself and would be undue because one would not be assured of the outcome (i.e. that ingestion of purified methylcellulose compositions with or without wheat bran, would lead to the prevention of cancer) because the questions concerning when to administer, to whom, how much, and whether the effects of fiber have to do with a general lifestyle or the additional compounds that are present in natural sources of fiber, have not been provided by present specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 21-27 and 29-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno (U.S. Patent 4,017,598; filing date Apr. 12, 1977) in view of ALVA-AMCO (Copy of Consumer Packaging of ALVA-Amco Pharmacal Cos., Inc.'s Fibre Naturale, 1996).

The claims are drawn to methods of administering methylcellulose at a viscosity of 4000 centipoise. The specification, as currently amended, teaches an example of methylcellulose having a mean viscosity of 4000 centipoise, with a range of 3000 to about 5,600. In light of the fact that viscosity can change with temperature and other conditions, and in light of the fact that the claims do not recite the conditions under which the viscosity is determined, the phrase in the claims of "having a viscosity of 4000 centipoise" is interpreted to include viscosities that are near to 4000 centipoise (such as, for example, "4,350 centipoise").

Ohno teaches methylcellulose preparations of readily disintegrable tablets, where the viscosity of the 2% by weight aqueous solution methylcellulose is 4,350 centipoise at 20°C. Ohno also teaches pharmaceutically acceptable carriers or diluents, tablet forms, comprising sugar, sucrose, and talc (see col. 4, lines 10-18; column 3, lines 6-27 and lines 44-68). Ohno clearly teaches that the methylcellulose preparations are intended for administration to humans (see col. 1, lines 26-39). Ohno fails to teach specific daily dosages. However, ALVA-AMCO

teaches that recommended daily dosages of methylcellulose preparations are in the range of 1800 mg to 2700 mg (6 to 9 caplets daily, each caplet having 300 mg methycellulose). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the Ohno methylcellulose preparations in a method of administration to a human, because Ohno clearly teaches that the methylcellulose preparations are intended for human consumption.

In previous Office actions, applicant has argued that rejections over the prior art are not valid because the prior art did not teach that the method of administration was useful for reduction of the incidence of colorectal cancer or breast cancer. This argument is not persuasive, because the claims and the prior art cited have the same active steps and the same population of people (healthy human beings) is being treated. Therefore, it appears that the intended use of the claimed methods does not alter the active method steps, the population being treated or the product being used in the claimed methods.

Applicants further argue that new uses of compositions are patentable and cite CAFC decision, Perricone v. Medicis Pharmaceutical Corporation, 432 F. 3d 1368 (Red. Cir., 2005). A review of Pericone shows that the reason the court found that the new method (treatment of sunburn) over the teaching of an old method, is the claim to this method contained the specific active step of applying the composition to sunburned skin, which was a specific teaching that was not present in the prior art, nor was it suggested, according to court decision. In contrast to the present rejection of the instant claims over the prior art, there is no specific difference in the active steps that has been pointed to by applicants. The differences in the prior art that applicants

point to is in the intended use of the claimed methods, not in the active steps. Therefore, the rejection is maintained for the reasons of record.

4. Claims 19, 21-27 and 29-34 remain rejected under 35 U.S.C. 103(a) as being obvious over Daggy (U.S. 6,350,469; issued Feb. 26, 2002; effective filing date Aug. 22, 1997).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Daggy teaches rapidly disintegrating methylcellulose tablet formulations of methylcellulose, where the viscosity is greater than 4000 centipoise, or is Dow Methocel A4M having a viscosity of about 3000 to about 5,600 centipoise (column 2, line 45 to column 3, line22). Daggy also teaches pharmaceutically acceptable carriers or diluents, tablet forms,

comprising magnesium stearate, sugar, gelatin, acacia or agar (see col. 4, line 62 to column 5, line 21). Daggy clearly teaches that the methylcellulose preparations are intended for administration to humans (see col. 2, lines 31-39). Daggy teaches specific daily dosages that are within the range of those claimed (see column 5, lines 22-40). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the Daggy methylcellulose preparations in a method of administration to a human, because Daggy clearly teaches that the methylcellulose preparations are intended for human consumption.

In previous Office actions, applicant has argued that rejections over the prior art are not valid because the prior art did not teach that the method of administration was useful for reduction of the incidence of colorectal cancer or breast cancer. This argument is not persuasive, because the claims and the prior art cited have the same active steps and the same population of people (healthy human beings) is being treated. Therefore, it appears that the intended use of the claimed methods does not alter the active method steps, the population being treated or the product being used in the claimed methods.

Applicants further argue that new uses of compositions are patentable and cite CAFC decision, Perricone v. Medicis Pharmaceutical Corporation, 432 F. 3d 1368 (Red. Cir., 2005). A review of Pericone shows that the reason the court found that the new method (treatment of sunburn) over the teaching of an old method, is the claim to this method contained the specific active step of applying the composition to sunburned skin, which was a specific teaching that was not present in the prior art, nor was it suggested, according to court decision. In contrast to the present rejection of the instant claims over the prior art, there is no specific difference in the

active steps that has been pointed to by applicants. The differences in the prior art that applicants point to is in the intended use of the claimed methods, not in the active steps. Therefore, the rejection is maintained for the reasons of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Please note: the earlier provisional rejection is now a rejection, because application 10/123,569 is now US Patent 7,132,114:

5. Claims 19, 21-27 and 29-34 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26 and 27 of US Patent 7,132,114. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of claims 26 and 27 comprise administering a tablet of claim 1, which

encompasses a tablet of claim 16, which is a rapidly disintegrating tablet comprising methylcellulose of a viscosity of > 4000 centipoise as the sole active ingredient (claim 1 recites that the viscosity is >1000 centipoise), and the instant claims are drawn to methods of treating humans consisting essentially of, in part, administering methylcellulose of viscosity that is 4000 centipoise. Claims 26 and 27 of US Patent 7,132,114 are drawn to methods of treating mammals for constipation, but the specification sets forth that the targeted users of this composition is "consumer", which reads on a human (see column 2, lines 20-21). Because the active steps of the methods of claims 26 and 27 are the same as the active steps of the instant methods, the methods of claims 26 and 27 anticipate the methods of the instant application even though the intended uses of the methods are different.

Applicants' traversal of this rejection is based on the grounds that the claims contained within US Patent 7,132,114 are pharmaceutical composition and/or process of making the pharmaceutical composition, whereas the claims of the present application are to a method of treatment. This is not found persuasive because in addition to the claims to compositions and methods of making the compositions, the patent contains claims to methods of treatment, as indicated in the previous Office action.

New Grounds of Rejection:

6. Claims 19, 21-27 and 29-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 92 of copending Application No. 10/993,550. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 92 of copending application no. 10/993,550

comprises a step where methylcellulose is ingested by a human. Therefore, the active step appears to be the same. The intended uses of the methods are different, because the intended use of the method of claim 92 is for the treatment of consitipation, but the difference in intended uses does not produce a difference in the active steps between the two methods. Claim 33 of copending application no. 10/993,550 recites that the methylcellulose has a viscositiy of greater than 4000 centipoise.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 19, 21-27 and 29-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60-63 of copending Application No. 10/993,272. Although the conflicting claims are not identical, they are not patentably distinct from each because claims 60-63 comprises a step where methylcellulose is ingested by a human. Therefore, the active step appears to be the same. The intended uses of the methods are different, because the intended use of the method of claims 60-63 is for the treatment of consitipation, but the difference in intended uses does not produce a difference in the active steps between the two methods. Claim 50 of copending application no. 10/993,272 recites that the methylcellulose has a viscositiy of greater than 4000 centipoise.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 19, 21-27 and 29-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 46-48 and 65-68 of copending Application No. 10/464,968. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 46-48 and 65-68 comprise a step where methylcellulose is administered to a human. Therefore, the active step appears to be the same. The intended uses of the methods are different, because the intended use of the method of claims 46-48 and 65-68 is for the treatment of consitipation, but the difference in intended uses does not produce a difference in the active steps between the two methods. Claims 16 and 61 of copending application no. 10/464,968 recite that the methylcellulose has a viscositiy of greater than 4000 centipoise.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 19, 21-27 and 29-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55-59 of copending Application No. 10/993,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 55-59 comprise a step where methylcellulose is ingested by a human. Therefore, the active step appears to be the same. The intended uses of the methods are different, because the intended use of the method of claims 55-59 is for the treatment of consitipation, but the difference in intended uses does not produce a difference in the active steps between the two methods. Claim 47 of copending application no. 10/993,983 recites that the methylcellulose has a viscositiy of greater than 4000 centipoise.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 19, 21-27 and 29-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 63-66 of copending Application No. 10/993,984. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 63-66 comprise a step where methylcellulose is ingested by a human. Therefore, the active step appears to be the same. The intended uses of the methods are different, because the intended use of the method of claims 63-66 is for the treatment of consitipation, but the difference in intended uses does not produce a difference in the active steps between the two methods. Claim 54 of copending application no. 10/993,984 recites that the methylcellulose has a viscositiy of greater than 4000 centipoise.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 19, 21-27, 29-48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kais (US 5,516,524; issued May 14, 1996; effective filing date is 12/20/1993) in view of Daggy (supra).

Within the scope of the claims are methods comprising the administration of a composition containing a water soluble, non-fermentable cellulose derivate which is methylcellulose having a viscosity of about 4000 centipoise in combination with an insoluble fiber which is wheat bran and a pharmaceutically acceptable carrier or diluent. The intended use

of the claimed methods is the reduction of the incidence of colorectal cancer or the reduction of the incidence of breast cancer. However, the intended uses recited in the claims do not appear to materially affect the active step recited of the claimed methods, which active step is administering to a human an effective amount of the composition. Because the intended use is to reduce the incidence of either colorectal or breast cancer, it appears that the population of humans is a population of humans that does not yet have cancer.

Kais teaches laxative compositions contains dioctyl sulfosuccinate and bul fiber slected from the group of psyllium, methylcellulose, polycarbophil, calcium polycbophil, bran, malt soup extract, karaya, guar gum and mixtures thereof (see abstract). Thus, Kais teaches a composition that comprises both methylcellulose and wheat bran. Kais also teaches a method comprising the step of administering the laxative compositions (see column 4, lines 21-24). Although the intended use of the method of Kais is the treatment of constipation, the active steps of Kais' method appears to be the same as the active step of the claimed methods, because both require the administration of a fiber composition. Kais fails to teach specifically that the methylcellulose has a viscosity of about 4000 centipoise. However, Daggy teaches the advantages of using methylcellulose in a laxative-composition, where the methylcellulose has a viscosity of about 4000 centipoise (see column 3, lines 5-22). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Kais to include methylcellulose that has a viscosity of about 4000 centipoise as taught in Daggy. One would have been motivated by the teachings of Daggy concerning the advantages of using methylcellulose of high viscosity.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
May 14, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER